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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,845	08/06/2003	Hiraku Murayama	011350-316	6514
21839	7590	05/25/2006	EXAMINER	
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			HOEKSTRA, JEFFREY GERBEN	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/634,845

Applicant(s)

MURAYAMA ET AL.

Examiner

Jeffrey G. Hoekstra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 2,5 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4 and 7-29 is/are rejected.
- 7) ☒ Claim(s) 1,3,4,11-13,16,21-23 and 26 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Notice of Amendment***

1. In response to the amendment filed on 03/14/2006, new claims 7-29 are acknowledged. The following new and reiterated grounds of rejection are set forth:

### ***Specification***

2. The examiner notes the amendment to the specification filed 03/14/2006.

### ***Claim Objections***

3. Claims 1,3,4,11-13,16,21-23 and 26 are objected to because of the following informalities:
  4. The term "substantially" in claims 1, 4, 16, and 26 is a relative term that appears to render the claims indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The tolerance for roughness of the welded portion of the wire member and the abutment orientation of the pre-welded wires is unclear.
  5. The term "at least" in claims 1 and 3 is a relative term that appears to render the claims indefinite. The term " at least" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The length of the coverage provided by the cover layer is unclear.

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6. Claims 1 and 3 recite the limitation "said wire member covering" in lines 7 and 6, respectively. There appears to be insufficient antecedent basis for this limitation in the claim.

7. The term "approximately" in claims 11-13 and 21-23 is a relative term that appears to render the claims indefinite. The term "approximately" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The degree of uniform thickness of the cover layer is unclear.

8. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-8, 10-14, 16-18, 20-24, and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Palermo et al (US 5,769,796).

11. For claim 1, Palermo et al discloses a guidewire 140 as broadly claimed comprising a first relatively stiff proximal wire member 142 (column 4 lines 26-31), a second relatively flexible distal wire member 146 with an elastic modulus larger than that of said first wire member (column 4 lines 26-31), a welded region 177 joining said first and second wire members (column 3 line 65 – column 4 line 50 and column 7 lines

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64 – 67 to column 8 lines 1-4), and a cover layer 179, 204 configured to cover at least said welded region (column 8 lines 31-37).

12. For claims 3 and 4, Palermo et al discloses a distal cover layer 206 comprised of a different material than said cover layer wherein said cover layer 179, 204 is formed, for example by dipping or spraying (column 14, lines 34-40), without heating said guidewire and furthermore wherein said distal-cover layer 206 is formed in such a manner that said guidewire is heated, for example by heat shrinking the polymer tubing (column 12 lines 36-37).

13. For claims 7, 8, 10-13, 17, 18, 20-23, and 27-29, Palermo et al discloses a cover layer 206 (e.g. an affixation member, a coating, or tie layer) distally disposed and comprised of a different material than said cover layer wherein said cover layer 179, 204 wherein said material: (a) reduces friction (column 4 lines 18-25); (b) is hydrophilic (column 13 lines 51-55); (c) is a fluorocarbon resin (column 15 lines 8-45); and (d) is a metallic member having an elastic modulus smaller than that of the first wire (column 7 line 40 – column 8 line 47). Palermo et al discloses said cover layer extending across the joined regions and comprising a uniform average thickness of 1 micron (column 15 lines 37-46). For clarification purposes examiner notes, 1000 Angstroms equals 100 nanometers equals 1 micron.

14. For claims 14 and 24, Palermo et al discloses a composite guidewire comprising different wire materials including: superelastic alloy wires and stainless steel wires.

***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 9, 16, 19, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palermo et al in view of Uchino et al (US 6,001,068).

18. For claims 9 and 19, Palermo et al discloses the claimed guidewire as aforementioned except for explicitly disclosing comprising the cover layer of silicone resin for reinforcing the welded region. Uchino et al teaches the use silicone resin as a cover layer 113 (column 6 lines 19-65). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composite guidewire as taught by Palermo et al, with Uchino et al for the purpose of configuring the mechanical properties of the guidewire for traversing tortuous vasculature.

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19. For claims 16 and 26, Palermo et al discloses the claimed guidewire as aforementioned except for explicitly disclosing welding the end faces of first and second wires in an orthogonal relationship with respect to the longitudinal axis of the guidewire via a butt resistance welding process. Uchino et al teaches the use of butt resistance welding in permanently coupling the end faces of first and second wires in an orthogonal relationship with respect to the longitudinal axis of the guidewire via a butt resistance welding process, as best seen in Figure 3.1-3.3 (column 7 line 60 – column 4 line 25). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composite guidewire as taught by Palermo et al, with butt resistance welding taught by Uchino et al for the purpose of fixedly coupling wires having varying mechanical properties to configure the guidewire for traversing tortuous vasculature.

20. Claims 15 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palermo et al in view of Reynolds et al (US 2003/0069521 A1). Palermo et al discloses the claimed guidewire as aforementioned except for explicitly disclosing the use of Co-Ni-Cr based alloy wire. Reynolds et al teaches the use of cobalt-based alloys in guidewire construction (paragraph 33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the composite guidewire as taught by Palermo et al, with the Co-Ni-Cr based alloy wire as taught by Reynolds et al for the purpose of coupling wires having varying mechanical properties to configure the guidewire for traversing tortuous vasculature.

***Response to Arguments***

21. Applicant's arguments with respect to claims 1, 3, and 4 have been considered but are moot in view of the new ground(s) of rejection.

22. Applicant's argue that Palermo does not anticipate, teach, or suggest welding a first wire to a second wire wherein said first wire has a smaller modulus of elasticity than said second wire. As broadly as claimed, Palermo discloses the claimed invention as positively identified above.

***Conclusion***

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is

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(571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JGH

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